IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA NEUROSCIENCE, INC., and YEDA RESEARCH AND DEVELOPMENT CO., LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AMNEAL PHARMACEUTICALS LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co., Ltd. (collectively "Plaintiffs" or "Teva") bring this action for patent infringement and declaratory judgment against Defendant Amneal Pharmaceuticals LLC ("Amneal").

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 8,232,250 ("the '250 patent") and United States Patent No. 8,399,413 ("the '413 patent"). This action arises out of the filing of an Abbreviated New Drug Application ("ANDA") by Amneal seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of COPAXONE® 40 mg/mL injection, Teva's innovative treatment for patients with relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '250 and '413 patents.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

3. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131.

5. Yeda Research and Development Co. Ltd. ("Yeda") is an Israeli company with its principal place of business at P.O. Box 95, Rehovot, 76100, Israel.

Amneal

6. Upon information and belief, Amneal is a limited liability company organized and existing under the laws of Delaware with a principal place of business at 400 Crossing Blvd., Third Floor, Bridgewater, NJ 08807-2863.

JURISDICTION AND VENUE

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) and § 1391.

10. Upon information and belief, this Court has personal jurisdiction over Amneal.

11. Upon information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware.

12. Upon information and belief, Amneal is registered to conduct business with the State of Delaware and maintains as a registered agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

13. Upon information and belief, Amneal is registered pursuant to Del. Code Ann. Tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware.

14. Upon information and belief, Amneal holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

15. Upon information and belief, Amneal markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

16. Upon information and belief, Amneal has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

17. Upon information and belief, Amneal has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Teva, which manufactures COPAXONE®, for sale and use throughout the United States, including the State of Delaware.

18. Upon information and belief, Amneal has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL throughout the United States, including in Delaware.

19. Amneal, after submitting its ANDA to the FDA, mailed a Paragraph IV Certification notice letter to Teva USA, a Delaware corporation.

20. Upon information and belief, this Court also has personal jurisdiction over Amneal because it has previously been sued in this district without challenging this Court's jurisdiction over it and has availed itself of this forum previously by asserting counterclaims for the purposes of litigating a patent dispute. *See, e.g., Endo Pharms. Inc. v. Amneal Pharms. LLC*, 14-cv-1382-RGA; *Forest Labs., Inc.* v. *Amneal Pharms. LLC*, 14-cv-508-LPS; *UCB, Inc.* v. *Amneal Pharms. LLC*, 13-cv-1208-LPS.

21. Upon information and belief, Amneal's systematic and continuous business contacts within Delaware render it at home in Delaware.

22. Upon information and belief, Amneal consented to jurisdiction in Delaware by registering to conduct business with the State of Delaware and maintaining a registered agent in Delaware.

23. Upon information and belief, this Court has personal jurisdiction over Amneal for the reasons stated herein, including, *inter alia,* Amneal's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Amneal at home in the forum.

BACKGROUND

The '250 Patent

24. The '250 patent, entitled "Low Frequency Glatiramer Acetate Therapy" was duly and legally issued on July 31, 2012.

25. Ety Klinger is the named inventor of the '250 patent.

26. Yeda is the sole owner by assignment of all rights, title and interest in the '250 patent.

27. Teva Ltd. is the exclusive licensee of the '250 patent.

28. The ’250 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “the Orange Book” (“Orange Book”), with respect to COPAXONE®.

29. A true and correct copy of the ’250 patent is attached as Exhibit A.

The ’413 Patent

30. The ’413 patent, entitled “Low Frequency Glatiramer Acetate Therapy” was duly and legally issued on March 19, 2013.

31. Ety Klinger is the named inventor of the ’413 patent.

32. Yeda is the sole owner by assignment of all rights, title and interest in the ’413 patent.

33. Teva Ltd. is the exclusive licensee of the ’413 patent.

34. The ’413 patent is listed in the Orange Book with respect to COPAXONE®.

35. A true and correct copy of the ’413 patent is attached as Exhibit B.

Teva’s COPAXONE® Product

36. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market a glatiramer acetate product known as COPAXONE®.

37. Teva USA is the holder of New Drug Application (“NDA”) number 02-0622, approved by the United States Food and Drug Administration (“FDA”) for the use of glatiramer acetate, marketed as COPAXONE®, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

38. Teva’s innovative COPAXONE® product is supplied as single-dose prefilled syringes that contain 40 mg/mL glatiramer acetate for injection, manufactured by Teva Pharmaceutical Industries Ltd., and marketed and sold in the United States by Teva Neuroscience, Inc.

The Amneal ANDA

39. Amneal filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® ("Amneal's Glatiramer Acetate Product"), prior to the expiration of the '250 and '413 patents.

40. FDA assigned the ANDA for Amneal's Glatiramer Acetate Product the number 207553.

41. Amneal also filed with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '250 and '413 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Amneal's Glatiramer Acetate Product ("Amneal's Paragraph IV Certification").

42. By letter dated January 23, 2015, Amneal notified Teva that it had filed ANDA No. 207553 seeking approval to market Amneal's Glatiramer Acetate Product prior to the expiration of the '250 and '413 patents ("Amneal Notice Letter").

43. Teva received the Amneal Notice Letter on or about January 26, 2015.

44. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Amneal Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,232,250 BY AMNEAL

45. The allegations of the proceeding paragraphs 1–44 are realleged and incorporated herein by reference.

46. The use of Amneal's Glatiramer Acetate Product is covered by one or more claims of the '250 patent.

47. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '250 patent.

48. Under 35 U.S.C. § 271(e)(2)(A), Amneal's submission to FDA of Amneal's ANDA to obtain approval for Amneal's Glatiramer Acetate Product with a Paragraph IV Certification related thereto before the expiration of the '250 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '250 patent.

49. Amneal was aware of the '250 patent when engaging in these knowing and purposeful activities and was aware that filing Amneal's ANDA with Amneal's Paragraph IV Certification with respect to the '250 patent constituted an act of infringement of the '250 patent.

50. Upon information and belief, Amneal seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Amneal's Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Amneal seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Amneal's Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

51. Upon information and belief, Amneal plans and intends to, and will, infringe the '250 patent immediately and imminently upon approval of Amneal's ANDA.

52. Upon information and belief, immediately and imminently upon approval of Amneal's ANDA, there will be direct infringement of the claims of the '250 patent under 35 U.S.C. § 271(a).

53. Upon information and belief, Amneal, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the '250 patent.

54. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of the '250 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

55. Upon information and belief, Amneal knows that Amneal's Glatiramer Acetate Product is especially made or adapted for use in infringing the '250 patent and that Amneal's Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Amneal, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '250 patent immediately and imminently upon approval of the Amneal's ANDA.

56. The foregoing actions by Amneal constitute and/or would constitute infringement of the '250 patent, active inducement of infringement of the '250 patent and/or contribution to the infringement by others of the '250 patent.

57. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the '250 patent, actively inducing infringement of the '250 patent and/or contributing to the infringement by others of the '250 patent.

58. Teva will be substantially and irreparably harmed by Amneal's infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if

Amneal is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Amneal's Glatiramer Acetate Product.

59. Amneal's activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,232,250 BY AMNEAL

60. The allegations of the proceeding paragraphs 1–59 are realleged and incorporated herein by reference.

61. Upon information and belief, Amneal plans to begin manufacturing, marketing, selling, offering to sell and/or importing Amneal's Glatiramer Acetate Product soon after FDA approval of Amneal's ANDA.

62. Such conduct will constitute direct infringement of one or more claims on the '250 patent under 35 U.S.C. § 271(a), inducement of infringement of the '250 patent under 35 U.S.C. § 271(b), and contributory infringement of the '250 patent under 35 U.S.C. § 271(c).

63. Amneal's infringing patent activity complained of herein is imminent and will begin following FDA approval of Amneal's ANDA.

64. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Amneal as to liability for the infringement of the '250 patent. Amneal's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

65. Upon information and belief, Amneal will knowingly and willfully infringe the '250 patent.

66. Teva will be irreparably harmed if Amneal is not enjoined from infringing the '250 patent.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,399,413 BY AMNEAL

67. The allegations of the proceeding paragraphs 1–66 are realleged and incorporated herein by reference.

68. The use of Amneal's Glatiramer Acetate Product is covered by one or more claims of the '413 patent.

69. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '413 patent.

70. Under 35 U.S.C. § 271(e)(2)(A), Amneal's submission to FDA of Amneal's ANDA to obtain approval for Amneal's Glatiramer Acetate Product with a Paragraph IV Certification related thereto before the expiration of the '413 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Amneal's Glatiramer Acetate Product would infringe one or more claims of the '413 patent.

71. Amneal was aware of the '413 patent when engaging in these knowing and purposeful activities and was aware that filing Amneal's ANDA with Amneal's Paragraph IV Certification with respect to the '413 patent constituted an act of infringement of the '413 patent.

72. Upon information and belief, Amneal seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Amneal's Glatiramer Acetate Product indicated for the treatment of patients with relapsing forms of multiple sclerosis. Further, upon information and belief, Amneal seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Amneal's Glatiramer Acetate Product, which will be indicated for administration three times per week with at least 48 hours between every injection.

73. Upon information and belief, Amneal plans and intends to, and will, infringe the ’413 patent immediately and imminently upon approval of Amneal’s ANDA.

74. Upon information and belief, immediately and imminently upon approval of Amneal’s ANDA, there will be direct infringement of the claims of the ’413 patent under 35 U.S.C. § 271(a).

75. Upon information and belief, Amneal, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced the infringement of one or more claims of the ’413 patent.

76. Upon information and belief, Amneal plans and intends to, and will, actively induce infringement of the ’413 patent when Amneal’s ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

77. Upon information and belief, Amneal knows that Amneal’s Glatiramer Acetate Product is especially made or adapted for use in infringing the ’413 patent and that Amneal’s Glatiramer Acetate Product is not suitable for substantial non-infringing uses. Upon information and belief, Amneal, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the ’413 patent immediately and imminently upon approval of the Amneal’s ANDA.

78. The foregoing actions by Amneal constitute and/or would constitute infringement of the ’413 patent, active inducement of infringement of the ’413 patent and/or contribution to the infringement by others of the ’413 patent.

79. Upon information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the ’413 patent, actively inducing infringement of the ’413 patent and/or contributing to the infringement by others of the ’413 patent.

80. Teva will be substantially and irreparably harmed by Amneal's infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Amneal is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Amneal's Glatiramer Acetate Product.

81. Amneal's activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,399,413 BY AMNEAL

82. The allegations of the proceeding paragraphs 1–81 are realleged and incorporated herein by reference.

83. Upon information and belief, Amneal plans to begin manufacturing, marketing, selling, offering to sell and/or importing Amneal's Glatiramer Acetate Product soon after FDA approval of Amneal's ANDA.

84. Such conduct will constitute direct infringement of one or more claims on the '413 patent under 35 U.S.C. § 271(a), inducement of infringement of the '413 patent under 35 U.S.C. § 271(b), and contributory infringement of the '413 patent under 35 U.S.C. § 271(c).

85. Amneal's infringing patent activity complained of herein is imminent and will begin following FDA approval of Amneal's ANDA.

86. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Teva and Amneal as to liability for the infringement of the '413 patent. Amneal's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Amneal's threatened imminent actions.

87. Upon information and belief, Amneal will knowingly and willfully infringe the '413 patent.

88. Teva will be irreparably harmed if Amneal is not enjoined from infringing the ’413 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully request the following relief:

(a) a judgment that the ’250 and ’413 patents are valid and enforceable;

(b) a judgment that Amneal’s submission of ANDA No. 207553 was an act of infringement of one or more claims of the ’250 and ’413 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Amneal’s Glatiramer Acetate Product prior to the expiration of the ’250 and ’413 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ’250 and ’413 patents;

(c) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Amneal ANDA No. 207553 or any product the use of which infringes the ’250 or ’413 patents, shall be a date that is not earlier than the expiration of the ’250 and ’413 patents;

(d) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Amneal and all persons acting in concert with Amneal from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Amneal’s Glatiramer Acetate Product, or any product the use of which infringes the ’250 or ’413 patents, or inducing or contributing to the infringement of the ’250 or ’413 patents until after the expiration of the ’250 and ’413 patents;

(e) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Amneal and all persons acting in concert with Amneal from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Amneal’s Glatiramer Acetate Product, or any

product or compound the use of which infringes the ’250 or ’413 patents, or inducing or contributing to the infringement of the ’250 or ’413 patents, until after the expiration of the ’250 and ’413 patents;

(f) an Order enjoining Amneal and all persons acting in concert with Amneal from seeking, obtaining, or maintaining approval of Amneal’s ANDA No. 207553 before the expiration of the ’250 and ’413 patents;

(g) an award of Teva’s damages or other monetary relief to compensate Teva if Amneal engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Amneal’s Glatiramer Acetate Product, or any product or compound the use of which infringes the ’250 or ’413 patents, or the inducement or contribution of the foregoing, prior to the expiration of the ’250 and ’413 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

(h) a judgment that this is an exceptional case and awarding Teva its attorneys’ fees under 35 U.S.C. § 285;

(i) an award of Teva’s reasonable costs and expenses in this action; and

(j) an award of any further and additional relief to Teva as this Court deems just and proper.

Respectfully submitted,

/s/ John W. Shaw

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